K033679

7.0 510(K) SUMMARY

Name of 510(k) Sponsor:	Centerpulse Spine-Tech, Inc.
Sponsor Address:	7375 Bush Lake Road Minneapolis, Minnesota 55439 Telephone Number: (952) 830-6284 Fax Number: (952) 832-5620
Sponsor Contact:	Tim Miller Director Clinical and Regulatory Affairs
Proprietary Name of Device:	CopiOs™ Bone Void Filler (BVF)
Generic/Classification Name:	Resorbable Calcium Salt Bone Void Filler
Classification Number:	Class II
Product Code:	89MQV
Legally Marketed Predicate Devices:	HEALOS Bone Graft Material (K012751); Collagraft Strip Bone Graft Matrix (K00122); Vitoss Scaffold Synthetic Cancellous Bone Void Filler (K994337); Pro Osteon Implant 500R Resorbable Bone Graft Filler/Bone Graft Material; 200R Resorbable Bone Graft Material (K980817, K990131, K0000515); Bio-Oss Collagen (K974399)

Device Description:

CopiOs™ BVF is a synthetic bone graft material consisting of mineralized, lyophilized collagen that has been formed into three-dimensional pads of various sizes for surgical implantation.

The CopiOs™ BVF product sponge consists of dehydrothermally (DHT) cross-linked bovine dermal collagen mixed with calcium phosphate salt. The pads are approximately 67% mineral by weight. The fibrous collagen mixed with the calcium phosphate salt is cast into sponges as described in this application. The average porosity of the product was determined to be 93.39%, which allows for favorable conditions for cell migration and adherence to the collagenous matrix. Further, the calcium phosphate provides the mineral required for osteogenesis and the specific CopiOs™ BVF formulation provides a pH environment conducive for osteoinduction.

Intended Use:

CopiOs™ BVF, in combination with autologous bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (ie, extremities, pelvis, spine) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs™ BVF is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

Technological Characteristics:

The intended use, composition, physical structure, and target population of CopiOs™ BVF are substantially equivalent to the FDA cleared and legally marketed predicate device, HEALOS.

- CopiOs™ BVF and the predicate device HEALOS are intended for the same use and target populations.
- CopiOs™ BVF and the predicate device HEALOS are sterile and provide a favorable environment for cell migration and adherence to the collagenous matrix.
- Both CopiOs™ BVF and the predicate device HEALOS are supplied as lyophilized products.
- Like HEALOS, the predicate device, CopiOs™ BVF contains approximately 33% type 1 bovine collagen while HEALOS contains 70%. Additionally, CopiOs™ BVF contains 67% calcium phosphate salt while HEALOS contains approximately 30% non-ceramic hydroxyappatite.
- CopiOs™ BVF and the predicate device HEALOS are resorbed following surgical implantation. The resorption rate between CopiOs™ BVF and HEALOS are similar as evidenced in the comparative rabbit radial defect study.

- CopiOs™ BVF and the predicate device HEALOS both promote bone regeneration and are remodeled into new bone at equivalent rates as demonstrated in the comparative rabbit radial defect study.

Conclusions:

The results from the tests conducted as described in detail in this submission support the substantial equivalence of CopiOs™ BVF to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

Ms. Kimberly Tokach
Senior Regulatory Affairs Specialist
Zimmer Spine
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K033679
Trade Name: CopiOs™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: April 28, 2004
Received: May 4, 2004

Dear Ms. Tokach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033679

Device Name: CopiOs™ BVF

Indications for Use:

CopiOs™ BVF, in combination with autologous bone marrow, is intended for use only for filling bone voids or gaps of the skeletal system (i.e., extremities, pelvis, spine) that are not intrinsic to the stability of the bone structure. These voids may be a result of trauma or creation by surgeon. CopiOs™ BVF is intended to be gently packed into the void or gap and will resorb during the course of the healing process.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033679